LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Nicotinell Spearmint
(nicotine)

SE/H/1103/01-02/MR

This module reflects the scientific discussion for the approval of Nicotinell Spearmint. The procedure was finalised at 2011-03-22. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Novartis Sverige AB has applied for a marketing authorisation for Nicotinell Spearmint, medicated chewing gum, 2 and 4 mg, claiming essential similarity to Nicorette, medicated chewing gum, 2 mg and 4 mg, marketed in Sweden by McNeil The product contains nicotine as active substance. For approved indications see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Nicotinell Spearmint is presented in the form of medicated chewing gums containing nicotine polacrilin corresponding to 2 or 4 mg of nicotine. The excipients are gum base (containing buthylhydroxytoluene), xylitol, calcium carbonate, sorbitol, mannitol, sodium carbonate anhydrous, sodium hydrogen carbonate, natural mint flavouring, polacrilin, glycerol, levomenthol, sucralose, gelatine, titanium dioxide, acesulfame potassium, carnauba wax and talc. Nicotinell Spearmint also contains novamint. The medicated chewing gums are packed in PVC/PVdC/aluminium blisters.

II.2 Drug Substance

Nicotine has a monograph in the Ph Eur.

Nicotine is a colourless or brownish viscous liquid which is soluble in water and miscible with anhydrous ethanol. The structure of nicotine has been adequately proven and its physico-chemical properties sufficiently described. The route of synthesis has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The active substance specification includes relevant tests and the limits for impurities/degradation products have been justified. The analytical methods applied are suitably described and validated.

Stability studies under ICH conditions have been conducted and the data provided are sufficient to confirm the retest period.

II.3 Medicinal Product

Nicotinell Spearmint medicated chewing gum is formulated using excipients described in the current Ph Eur, except for the gum base, natural mint flavours, sucralose and novamint Spearmint which are controlled according to acceptable in house specifications. All raw materials used in the product are of vegetable origin or has demonstrated compliance with Commission Directive 2003/63/EC and the NfG on Minimising the risk of transmitting Animal Spongiform Encephalopathy Agents via human and veterinary medicinal products (EMEA/410/01).

The product development has taken into consideration the physico-chemical characteristics of the active substance.

The manufacturing process has been sufficiently described and critical steps identified. Results from the process validation studies confirm that the process is under control and ensure both batch to batch reproducibility and compliance with the product specification.

The tests and limits in the specification are considered appropriate to control the quality of the finished product in relation to its intended purpose.

Stability studies under ICH conditions have been performed and data presented support the shelf life claimed in the SPC, when stored below 25°C.

III. NON-CLINICAL ASPECTS

III.1 Discussion on the non-clinical aspects

Since this product has been shown to be essentially similar and refer to a product approved based on a full application with regard to preclinical data, no further such data have been submitted or are considered necessary.

IV. CLINICAL ASPECTS

IV.1 Pharmacokinetics

The first approved Nicotinell gums demonstrated bioequivalence with the originator Nicorette. There is no formal bioequivalence study performed with the actual formulation in this application. Small in vivo studies that have been used in the in vitro-in vivo correlations (IVIVC) have been performed. For the actual chewing gums in this application, in vitro/in vivo correlations have been used to demonstrate similarity with the Nicotinell coated chewing gums.

IV.2 Discussion on the clinical aspects

Since this product has been shown to be essentially similar and refer to a product approved based on a full application with regard to clinical efficacy/safety data, no further such data have been submitted or are considered necessary.

V. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

User consultation

A user consultation with target patient groups on the package information leaflet (PIL) has been performed on the basis of a bridging report making reference to Nicotinell Liquorice medicated chewing-gum, UK/H/0409/001-002/II/016. The bridging report submitted by the applicant has been found acceptable.

The risk/benefit ratio is considered positive and Nicotinell Spearmint, medicated chewing gum, 2 and 4 mg, is recommended for approval.

VI. APPROVAL

The Mutual recognition procedure for Nicotinell Spearmint, medicated chewing gum, 2 and 4 mg, was successfully finalised on 2011-03-22.

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Public Assessment Report – Update

Scope	Procedure number	Product Information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval	Assessment report attached
						Y/N (version)

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